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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,801	08/18/2003	Sanjay Bhanot	RTS-0678US	4755

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EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,801	BHANOT ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,22-40,44 and 49-57* is/are pending in the application.

4a) Of the above claim(s) *18,23-40 and 49-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,22 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/03; 10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-17, 22 and 41-48, SEQ ID NO: 35 that is antisense targeted to a coding region of the diacylglycerol acyltransferase 2 (SEQ ID NO: 4) (as set forth in claim 44), in the reply filed on 6/27/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of the Application

2. Claims 1-18, 22-40, 44 and 49-57 are pending in this application. Claims 19-21, 41-43 and 45-48 were cancelled by Applicant in the communication filed 6/27/05. Claims 18, 23-40 and 49-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-17, 22 and 44 are currently under examination.

Information Disclosure Statement

3. References AO, AP and AR, listed on the information disclosure statement filed 8/13/2003, fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the complete reference has not been provided. The abovementioned IDS has been placed in the application file, but the information referred to therein as References

AO, AP and AR have not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The specification as filed states in regards to oligonucleotides, that, "Thus, "specifically hybridizable" and "complementary" are terms which are used to indicate a sufficient degree of precise-pairing or complementarity over a sufficient number of nucleobases such that stable and specific binding occurs between the oligonucleotide and a target nucleic acid" (section [0031]). The specification as filed distinguishes between what is meant by specifically hybridizable in the context of an oligonucleotide

and an oligonucleotide that is required to be antisense wherein it states that, "An antisense compound is specifically hybridizable when binding of the compound to the target nucleic acid interferes with the normal function of the target nucleic acid to cause a loss of activity, and there is a sufficient degree of complementarity to avoid non-specific binding of the antisense compound to non-target nucleic acid sequences under conditions in which specific binding is desired, i.e., under physiological conditions in the case of in vivo assays or therapeutic treatment, and under conditions in which assays are performed in the case of in vitro assays" (section [0029]).

Therefore, the following prior art rejections are applied based on a reasonable interpretation of claim 1 which considers that the claimed oligonucleotide is not required to be an antisense. This interpretation is supported by the specific "antisense" limitation that is set forth in dependent claims 5 and 44, thereby distinguishing between an oligonucleotide and an antisense oligonucleotide.

Claims 1, 4, 6, 9-13 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardin et al. (U.S. Patent 6,083,695). The instant invention as set forth in claim 1 is drawn to a compound 8 to 80 nucleobases in length that is specifically hybridizable to instant SEQ ID NO: 4 and comprises at least an 8 nucleobase portion of instant SEQ ID NO: 35 (claim 1). Dependent claims 4, 6, 9-13 and 22 require that the compound of claim 1 comprise an oligonucleotide (claim 4), a DNA oligonucleotide (claim 6), wherein at least a portion of the compound hybridizes with RNA (claim 9), wherein the compound has at least 80% or 90% or 95% or 99% complementarity with

instant SEQ ID NO: 4 (claims 10-13) and wherein the compound is comprised in a kit (claim 22).

Hardin et al. disclose SEQ ID NO: 57 (col. 53), a compound that is an 8 nucleobase DNA oligonucleotide that is 100% complementary to nucleotide positions 919 to 926 within the coding region of instant SEQ ID NO: 4. SEQ ID NO: 37 of Hardin et al. comprises an 8 nucleobase portion of instant SEQ ID NO: 35 that is TTGCCACT and is disclosed as comprised in an octamer library (col. 7) which is a disclosure of a kit comprising the instantly claimed compound.

5. Claims 1-4, 6, 9 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Marmaro et al. (U.S. Patent 6,605,451). The invention as set forth in claims 1, 4, 6, 9 and 22 is relied upon as above. Dependent claims 2 and 3 require particular length limitations of the compound of claim 1.

Marmaro et al. disclose SEQ ID NO: 38 (col. 10, Table 1), a compound that is an 18 nucleobase DNA oligonucleotide that is 72% complementary to nucleotide positions 909-927 of the coding region of instant SEQ ID NO: 4. 72% complementarity is interpreted herein as being sufficient complementarity to be specifically hybridizable to instant SEQ ID NO: 4. SEQ ID NO: 38 of Marmaro et al. comprises at least an 8 nucleobase portion of instant SEQ ID NO: 35 that is TTCTTACCC and is disclosed as comprised in a kit (col. 4, lines 41-50).

6. Claims 1-9, 14-17, 22 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al. (U.S. Patent 6,284,538). The invention as set forth in claims 1-4, 6, 9 and 22 is relied upon as above. Dependent claims 7, 8 and 14-17 require that the oligonucleotide of claim 4 be an RNA oligonucleotide or a chimeric oligonucleotide (claims 7 and 8 respectively) and that the compound of claim 1 "having" (which is read in the context of the specification as "comprises") at least one modified internucleoside linkage, sugar or base (claim 14) at least one 2'-O-methoxyelthy sugar moiety (claim 15), at least one phosphorothioate linkage (claim 16) and at least one 5-methylcytosine (claim 17). Claims 5 and 44 require the compound of claim 1 comprise an antisense oligonucleotide (claim 5) and that the compound comprises an antisense nucleic acid molecule that is specifically hybridizable with the coding region of instant SEQ ID NO: 4.

Monia et al. disclose SEQ ID NO: 47 (col. 45, Table 2), an antisense compound that is an 18 nucleobase modified chimeric gapmer that comprises phosphorothioate internucleoside linkages, 2'-O-methoxyelthy sugar moieties and 5-methylcytosines that is 66.7% complementary to nucleotide positions 909-927 of the coding region of instant SEQ ID NO: 4. 66.7% complementarity is interpreted herein as being sufficient complementarity to be specifically hybridizable to instant SEQ ID NO: 4, in the context of both oligonucleotides and antisense compounds (as set forth in the specification and outlined above). SEQ ID NO: 47 of Monia et al. comprises at least an 8 nucleobase portion of instant SEQ ID NO: 35 that is TTCTTACCC and is disclosed as comprised in a kit (col. 13, lines 17-20).

Claim Rejections - 35 USC § 102 or 35 USC § 103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 4-6, 9-13, 22 and 44 are rejected under 35 U.S.C. 102(b) or 35 USC 103(a) as being anticipated by or obvious over Hardin et al. (U.S. Patent 6,083,695). The invention set forth in claims 1, 4-6, 9-13, 22 and 44 are relied upon as above.

The disclosure of Hardin et al. is relied upon as above.

Furthermore, since the prior art oligonucleotide meets all the structural limitations of the claims, the prior art oligonucleotide comprises compound that is specifically hybridizable to instant SEQ ID NO: 4 that is an antisense oligonucleotide or antisense nucleic acid, absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and

for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant invention is anticipated or obvious over Hardin et al. (U.S. Patent 6,083,695).

9. Claims 1-6, 9, 22 and 44 are rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Marmaro et al. (U.S. Patent 6,605,451). The invention set forth in claims 1-6, 9, 22 and 44 is relied upon as above.

The disclosure of Marmaro et al. is relied upon as above.

Furthermore, since the prior art oligonucleotide meets all the structural limitations of the claims, the prior art oligonucleotide comprises compound that is specifically hybridizable to instant SEQ ID NO: 4 that is an antisense oligonucleotide or antisense nucleic acid, absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and

for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant invention is anticipated or obvious over Marmaro et al. (U.S. Patent 6,605,451).

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba